MAY 2 8 2004

Akers Laboratories, Inc.
HealthTEST® Heparin/Platelet Factor 4 Antibody Assay
510(k) Notification

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K040293.

807.92 (a)(1):

Name: Akers Laboratories, Inc.
Address: 201 Grove Road
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Phone: (856) 848-8698
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Contact: Barbara A. Bagby

807.92 (a)(2): Device Name – trade name and common name, and classification

Trade name: HealthTEST® Heparin/Platelet Factor 4 Antibody Assay

Common name: Platelet Factor 4 Assay

Classification: 21 CFR 864.7695
Product Code: LCO

807.92 (a)(3): Identification of the legally marketed predicate device

HealthTEST® Heparin/Platelet Factor 4 Antibody Assay is substantially equivelant to the GTI PF4 Elisa Assay, Genetic Testing Institute, Waukesha, WI; K983379

807.92 (a)(4): Device Description

The HealthTEST® Heparin/Platelet Factor 4 Antibody Assay consists of two components: a Mini-reactor device containing a membrane filtration system and a results window, and a dispenser containing reaction reagents.

807.92 (a)(4): Device Description (continued)

The Mini-reactor contains a reaction well that allows the sample to react with the reagents. The sample is added to the reaction well followed by the reagents contained in the reagent dispenser. The reagents contain microparticles coated with purified PF-4 protein as well as additional enhancing agents designed to promote rapid agglutination of the particles in the presence of specific antibodies in the test sample.

Once the reagents have reacted with the sample in the reaction well, the reaction mixture automatically collects over the membrane filtration system. This system acts to filter agglutinated particles, while allowing non-agglutinated particles to pass through. Thus, an agglutinated, reactive sample will be trapped within the membrane. Since the dyed particles are trapped by this filter, no particles and hence no color, are able to migrate past the positive/negative line on the results window. Conversely, a non-agglutinated, non-reactive sample will pass through the membrane filter and into the wicking layers, and no color will migrate past the positive/negative line.

807.92 (a)(5): Intended use

The HealthTEST® Heparin/Platelet Factor 4 Antibody Assay is an *in vitro* diagnostic device designed for the detection of antibodies to Platelet Factor 4 complexed to polyanionic compounds such as polystyrene. These antibodies are found in some patients undergoing heparin therapy.

807.92 (a)(6): Technological Similarities and Differences to Predicate

The following chart exhibits similarities and differences between the HealthTEST® Heparin/Platelet Factor 4 Antibody Assay and the GTI PF4 Elisa Assay:

CHARACTERISTIC	HealthTEST® Heparin/Platelet Factor 4 Antibody Assay	GTI PF4 ELISA K983379
Intended Use	Detects antibodies to the Heparin/PF4 complex in patient's circulation	Detects antibodies to the Heparin/PF4 complex in patient's circulation
Indications for Use	Used as an *in vitro* diagnostic kit by hematology, coagulation or other pathology laboratories to assist in screening patient samples for the presence of heparin-associated antibodies commonly found in patients with heparin-induced thrombocytopenia or thrombosis.	Used as an *in vitro* diagnostic kit by hematology, coagulation or other pathology laboratories to assist in screening patient samples for the presence of heparin-associated antibodies commonly found in patients with heparin-induced thrombocytopenia or thrombosis.
Assay type	Serology	Serology
Sample Matrix	Serum, plasma	Serum
Methodology	Immunoassay, Particulate ImmunoFiltration Assay (PIFA)	Immunoassy, Enzyme-linked Immunosorbent Assay (ELISA)
Testing Environment	Professional	Professional
Analyte Detection	Antibody to PF-4 complexed with polyanionic compounds	Antibody to PF-4 complexed with polyanionic compounds
Specificity	90.1% (plasma) 98.1% (serum)	89.9% (serum)
Sensitivity	91.3% (serum & plasma)	95.2% (serum)
Throughput	Individual	Batch testing
Risk to Patient	Minimal to moderate, interpreted with other clinical findings	Minimal to moderate, interpreted with other clinical findings

The differences in the two testing platforms do not raise new issues of safety and effectiveness.

807.92 (b)(1): Brief Description of Non-clinical data

Two studies were performed to evaluate the performance of the HealthTEST® Heparin/Platelet Factor 4 Antibody Assay compared to commercially available, standard laboratory methods using fresh samples originating from field sources.

Specificity and Sensitivity

Study # 1 Plasma

		ELISA	
		Positive	Negative
HealthTEST	Positive	21	15
	Negative	2	137

Specificity = 90.1%
Sensitivity = 91.3%
Overall Agreement = 90.3%

Study #2 Serum

		ELISA	
		Positive	Negative
HealthTEST	Positive	21	3
	Negative	2	153

Specificity = 98.1%
Sensitivity = 91.3%
Overall Agreement = 97.2%

807.92 (b)(2): Brief Description of Clinical Data

Not applicable, all testing performed via bench by independent laboratory and/or internally.

807.92 (b)(3): Conclusions from Non-clinical and Clinical Testing

The HealthTEST® Heparin/Platelet Factor 4 Antibody Assay was evaluated for non-clinical and clinical performance characteristics in comprehensive studies. These studies demonstrated that the test is safe and effective for intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 2 8 2004

Ms. Barbara A. Bagby
Director, Quality Assurance & Regulatory Affairs
Akers Laboratories, Inc
201 Grove Rd.
Thorofare, NJ 08086

Re: k040293
Trade/Device Name: HEALTHTEST® Heparin/Platelet Factor 4 Antibody Assay
Regulation Number: 21 CFR 864.7695
Regulation Name: Platelet Factor 4 radioimmunoassay
Regulatory Class: Class II
Product Code: LCO
Dated: April 30, 2004
Received: May 3, 2004

Dear Ms. Bagby:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K040293

Device Name: HEALTHTEST® Heparin/Platelet Factor 4 Antibody Assay

Indications for Use:

The HEALTHTEST® Heparin/Platelet Factor 4 Antibody Assay is a qualitative *in vitro* diagnostic device designed for the detection of antibodies to the Platelet Factor 4 complexed to polyanionic compounds such as polystyrene. These antibodies are found in some patients undergoing heparin therapy.

The risk of heparin induced thrombocytopenia (HIT) is greatly increased in patients with recent exposure to heparin. The presence of heparin/PF-4 antibody is associated with patients at risk for HIT, and is rapidly becoming a standard of care in hematology and cardiology. The need for a rapid test to detect these antibodies from serum or plasma in less than 5 minutes is highly desired. This rapid manual assay should be easily performed when STAT results are required.

Prescription Use ✓ OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE AS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040293